

# Perioperative ischemic evaluation study (POISE study)

<b>Submission date</b> 19/08/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 19/08/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/02/2009	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Philip Devereaux

**Contact details**  
Clinical Epidemiology & Biostatistics  
McMaster University Health Sciences Centre  
Room 2C8, 1200 Main Street West  
Hamilton, Ontario  
Canada  
L8N 3Z5  
+1 905 525 9140 ext. 22063  
philipj@mcmaster.ca

## Additional identifiers

**ClinicalTrials.gov (NCT)**  
NCT00182039

**Protocol serial number**  
MCT-50851, ACTRN012605000308695

## Study information

## **Scientific Title**

### **Acronym**

POISE

### **Study objectives**

Perioperative metoprolol will reduce the 30 day risk of major cardiovascular events in patients undergoing noncardiac surgery.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

McMaster University Research Ethics Board approved on 25th April 2002

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Prevention

### **Health condition(s) or problem(s) studied**

Cardiovascular

### **Interventions**

Patients will be randomly assigned to either the experimental intervention of oral metoprolol or the control intervention, a placebo. Patients will receive their first dose of metoprolol CR or placebo two to four hours pre-operatively at a strength of 100 mg (1/2 of a 200 mg tablet). Patients will then receive their second dose of their assigned intervention during the first 6 hours or at 6 hours post surgery. Twelve hours after the second post-op dose, patients will start taking a daily dose of 200 mg of either metoprolol CR or placebo for a duration of 30 days post surgery.

For further information, please contact Dr Devereaux at the address listed below or Dr Homer Yang at Ottawa Hospital ([hyang@ottawahospital.on.ca](mailto:hyang@ottawahospital.on.ca)).

### **Intervention Type**

Drug

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Metoprolol

### **Primary outcome(s)**

Cardiac death at 30 days, nonfatal myocardial infarction (MI), and nonfatal cardiac arrest

**Key secondary outcome(s)**

1. Length of hospital stay
2. Length of stay in an ICU/CCU
3. Revascularisation procedures (i.e. coronary artery bypass surgery and percutaneous transluminal coronary angioplasty)
4. Pulmonary oedema
5. Clinically significant atrial fibrillation
6. Stroke
7. Total mortality
8. Rehospitalisation for cardiac reasons
9. Myocardial infarction
10. Nonfatal cardiac arrest
11. Cardiovascular mortality
12. Clinically significant hypotension
13. Clinically significant bradycardia

**Completion date**

01/04/2007

## **Eligibility**

**Key inclusion criteria**

1. Greater than or equal to 45 years of age, either sex
2. Have an expected length of stay greater than or equal to 24 hours
3. Fulfill any one of the following six criteria:
  - 3.1. Coronary artery disease
  - 3.2. Peripheral vascular disease
  - 3.3. History of stroke due to atherothrombotic disease
  - 3.4. Hospitalisation for congestive heart failure within 3 years of randomisation
  - 3.5. Undergoing major vascular surgery
  - 3.6. Any three of the following seven criteria: scheduled for high risk surgery (i.e. intraperitoneal or intrathoracic), emergency/urgent surgery, any history of congestive heart failure, history of a transient ischaemic attack (TIA), diabetes and currently on an oral hypoglycaemic agent or insulin therapy, preoperative serum creatinine greater than 175  $\mu\text{mol/l}$  (greater than 2.0 mg/dl), or age greater than 70 years
4. Are able to give written consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

## Key exclusion criteria

1. Contradiction to metoprolol including any of the following: significant bradycardia (heart rate less than 50 beats per minute); second or third degree heart block without a pacemaker, asthma that has been active within the last decade, and history of chronic obstructive pulmonary disease (COPD) with bronchospasm on pulmonary function tests
2. Clinical plan to use a beta-blocker preoperatively or during the first 30 postoperative days prior adverse reaction to a beta-blocker
3. Coronary artery bypass graft (CABG) surgery with complete revascularisation in the preceding 5 years and no evidence of cardiac ischaemia since the CABG surgery
4. Patients undergoing low risk surgical procedures (potential examples include transurethral procedures [transurethral prostatectomies {TURPs}, stone baskets etc.], ophthalmologic procedures under topical or regional anaesthesia [cornea transplants, cataract surgery etc.], and surgeries with limited physiological stresses [digital re-implantation, nerve repairs etc.])
5. Concurrent use of verapamil
6. Prior enrolment in this trial

## Date of first enrolment

01/09/2002

## Date of final enrolment

01/04/2007

## Locations

### Countries of recruitment

Australia

Canada

### Study participating centre

Clinical Epidemiology & Biostatistics

Hamilton, Ontario

Canada

L8N 3Z5

## Sponsor information

### Organisation

McMaster University (Canada)

### ROR

<https://ror.org/02fa3aq29>

# Funder(s)

## Funder type

Research organisation

## Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-50851)

## Funder Name

National Health and Medical Research Council (NHMRC) (Australia)

## Alternative Name(s)

National Health and Medical Research Council, Australian Government, NHMRC National Health and Medical Research Council, NHMRC

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

Australia

## Funder Name

Australia Clinical Trials Grant (Australia)

## Funder Name

British Heart Foundation (UK)

## Alternative Name(s)

the\_bhf, The British Heart Foundation, BHF

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Trusts, charities, foundations (both public and private)

## Location

United Kingdom

Funder Name  
Astra Zeneca (International)

## Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	31/05/2008		Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes